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TITLE: Improved Training Program for Fall Prevention of Warfighters with Lower Extremity Trauma

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14. ABSTRACT
Overseas Contingency Operations have produced many U.S. warfighters with lower extremity injuries. Although the U.S. military has access to state-of-the-art treatment and devices, warfighters with extremity trauma still struggle to regain full functional capabilities. A key factor that limits the ability of individuals with lower extremity trauma to achieve maximum functional capabilities is falls. Falls have serious consequences including loss of confidence, fear of falling, and injury. Warfighters with lower extremity trauma need to face the risk of falling and overcome that fear. After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay healing. When individuals trip or slip, they are still likely to fall and injure themselves, in spite of advances in rehabilitation care. The proposed project describes a secondary rehabilitation program, implemented after traditional therapy, and designed to reduce falls in warfighters with amputations or salvaged limbs. The goals of this research effort are to augment existing rehabilitation with a novel, demonstrably successful fall-prevention training method to help warfighters return to full high-level functional capabilities and emotional wellness, and to decrease the time required to either return to active duty or to a productive, active civilian life. The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 4-week period. In this first year, we have finalized the protocol, developed standard operating procedures, established CRADAs, finalized case report forms and a REDCap database for data collection, and obtained IRB approvals.

15. SUBJECT TERMS
Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy

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1. INTRODUCTION

After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay return to active duty or to a productive, active civilian life. Following a trip or slip, many warfighters are still likely to fall and injure themselves, in spite of advances in rehabilitation care. Adaptations due to the loss of function are necessary, which limits physical performance and reduces quality of life. The proposed project describes a secondary rehabilitation program, implemented after and as augmentation to existing rehabilitation by providing advanced fall-prevention training, to help warfighters return to full high-level functional capabilities and emotional wellness, and to decrease the time required to either return to active duty or to a productive, active civilian life. The proposed novel training method has the potential to change the standard of care for lower extremity limb trauma.

2. **KEYWORDS:** Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy,

3. ACCOMPLISHMENTS

- **What were the major goals of the project?**
  Our study has three main objectives, which will be achieved over a three-year timeframe. First, we will implement a novel postural perturbation training program in the three DOD Medical Treatment facilities. This rehabilitation protocol will be provided to active-duty service members who have suffered combat-related lower limb trauma, specifically amputations or salvaged limbs. Second, we will assess whether the benefits of improved motor skills induced by the rehabilitation protocols can be retained following training. Third, we will identify, evaluate, and implement existing low cost methods for measuring trunk control that can be used in lieu of substantially more expensive fixed motion capture systems. This will ensure that the rehabilitation program can be transitioned to clinical settings.

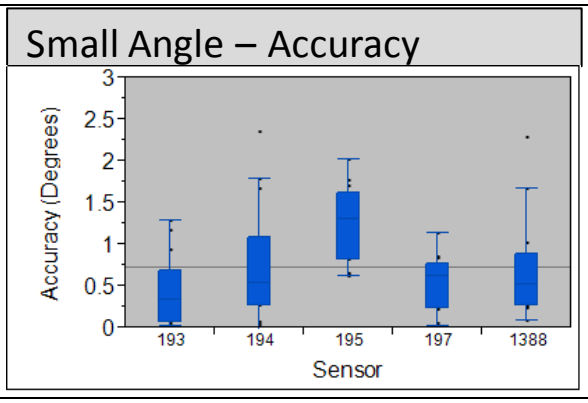
- **What was accomplished under these goals?**
  The primary goals in this first year of the study were to establish the project infrastructure and obtain regulatory review of the study protocol.

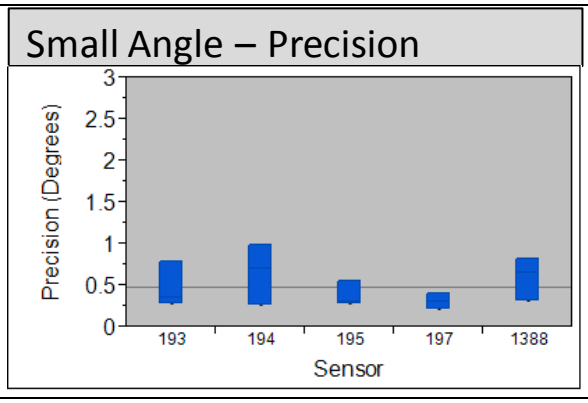
  Major activities:
  A CRADA has been established between the Naval Medical Center San Diego (NMCSD) and Mayo Clinic (Mayo). Another CRADA is currently being finalized between the Center for the Intrepid - San Antonio (CFI), Walter Reed National Military Medical Center (WRNMMC), and Mayo.

  The fall prevention training program utilizes a microprocessor-controlled treadmill to deliver task specific training perturbations. Equipment requisitions have been submitted for treadmill purchases by CFI and WRNMMC. This equipment is central to the perturbation training program. During each training session, the task difficulty is increased as the patient's motor skill progresses. Three types of perturbations are delivered to subjects during each training session. Two "static" and one "dynamic" perturbations are used: (1) *static step*: the belt is moved while the patient is standing still on the treadmill and the patient responds with a single forward step; 2) *static walk*: the belt is moved while the patient is standing on the treadmill and the patient responds with multiple forward steps: and 3) *eTRIP*: a perturbation is delivered at a random time while the subject is walking on the treadmill and the subject must respond with multiple forward steps. The computer software has been written to provide these disturbances for the treadmill at NMCSD. A User's Guide has also been produced for this software.

Assessment of the training program effectiveness will initially be done using a perturbation testing protocol in a Computer Assisted Rehabilitation Environment (CAREN, Motek Medical BV, Amsterdam). This fully immersive virtual environment comprises a 6 degree-of-freedom motion platform with an imbedded instrumented dual belt treadmill and integrated force plates. The platform is surrounded by a 180 degree screen. During the testing protocol perturbations simulating a trip in the natural environment are delivered. Six perturbations (3 left limb/3 right limb) are delivered in a randomized order while the subject walks for five to six minutes at a velocity standardized to leg length. This assessment of the rehabilitative program will be performed before and after the training on the computerized treadmill. The key outcome variables are peak trunk flexion and trunk velocity between time of treadmill perturbation and recovery step completion. These variables have been shown to determine the likelihood of a fall.

A low cost method for measuring trunk control has been identified. This method uses an inertial measurement unit (IMU). The specific IMU to be used (Opal, APDM, Portland, OR) has been identified. Testing of five representative sensors has been completed to assess the accuracy and precision under both static and dynamic conditions. The static testing assessed the sensor's ability to capture orientation data for both small (0-15°) and large (0-180°) angular displacements over short time periods. Dynamic testing assessed the sensor's ability to obtain angular velocity measures for a representative range of human functionality. The tested velocity ranged up to 2,000 degrees/second (dps) (for the x- and y-axis) and 1,500 dps for the z-axis (manufactures specified maximum range). The 2,000 dps represents the approximate maximum velocity for the shoulder velocity of professional baseball pitchers and also the angular velocity of a sprinters' knee. We also included testing at 150 dps and 300 dps, the range we are expecting for trunk velocity in the perturbation testing. The results demonstrated that for both static small and large angular displacements, the average sensor accuracy and precision were both within 0.7 degrees (Figure 1). The dynamic angular velocity testing of the five sensors revealed an average accuracy of 6.4 dps and an average precision of 0.3 dps. One of the sensors appeared to be an outlier (Figure 2). With this outlying sensor excluded, the average four sensor accuracy was 2.3 dps and precision was 0.2 dps. These results confirm that the sensor is appropriate for the planned testing. Since the testing has begun, a new generation of sensors has been released by the company. These new sensors are being ordered for the testing at all participating sites. Once the sensors are received, their performance will be assessed using this same testing protocol prior to using them in the study.





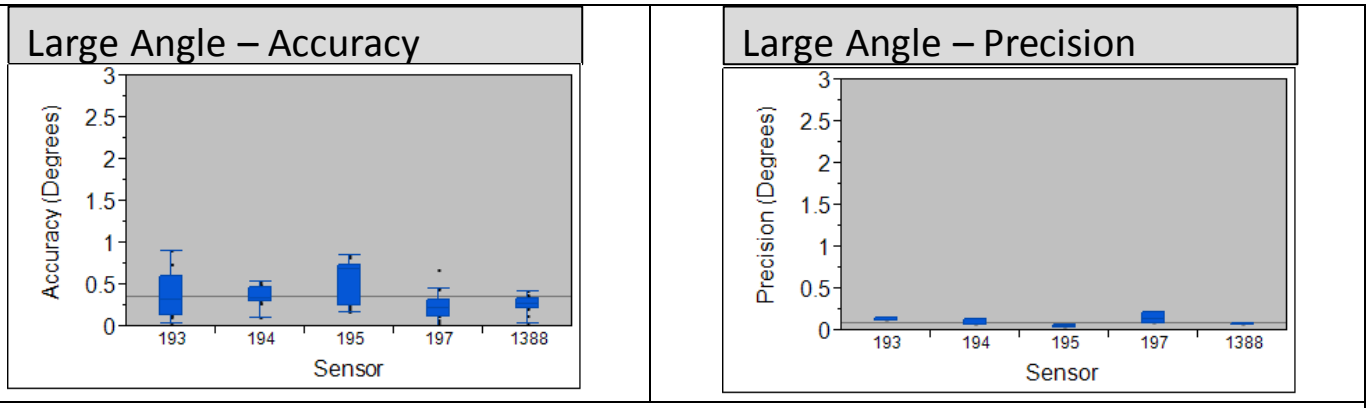


Figure 1. Box and whisker plots for (a) small and (b) large angle static validation testing of both accuracy and precision. Data from individual sensors tested is shown.

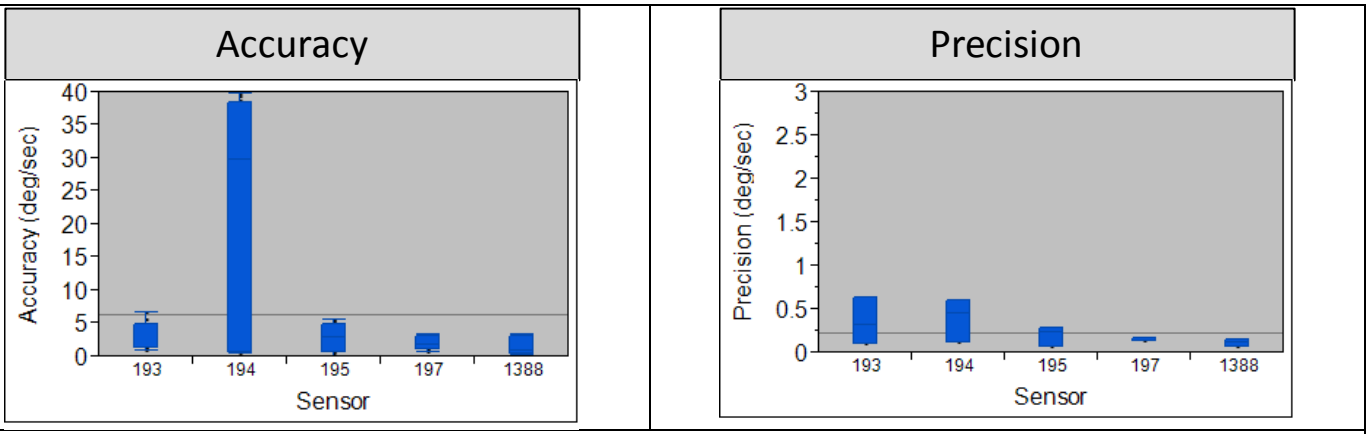


Figure 2. Box and whisker plots for the dynamic accuracy and precision validation testing. Data from individual sensors tested is shown.

The research program will have two study protocols. The first protocol is a comparison of IMU sensors to motion capture for measuring trunk motion and velocity during treadmill disturbance activities. This protocol has received IRB and HRPO approval. The protocol will begin data collection after the accuracy and precision testing of the new version of the IMUs has been completed. See previous paragraph. The second protocol is to assess the extent to which the novel fall-prevention training program reduces falls and fall-risk and enhances acquisition of functional capabilities for patients with lower extremity trauma. This protocol has been reviewed and approved at Mayo. It has been submitted to the NMCSD IRB and is scheduled for review on October 3.

The SOPs have been developed for the study. The case report forms have been established**.** A REDCap database has been created for data collection from all sites. The database will enable electronic capture of patient reported outcomes and completion of fall questionnaires.

- **What opportunities for training and professional development has the project provided?**
  Nothing to report.

- **How were the results disseminated to communities of interest?**
  Nothing to report.

- **What do you plan to do during the next reporting period to accomplish the goals?**

- The postural perturbation software will be modified for the treadmills at CFI and WRNMMC.
- Study staff will be hired and trained on operation of the treadmill system.
- The second protocol will be submitted to HRPO for approval.
- After HRPO approval is obtained, subject recruitment and enrollment will commence.
- The accuracy and precision of the IMU used in this study is being quantified. A paper will be submitted on these findings.

4. IMPACT

- **What was the impact of the development of the principal discipline(s) of the project?**
  Nothing to report.

- **What was the impact on other disciplines?**
  Nothing to report.

- **What was the impact on technology transfer?**
  Nothing to report.

- **What was the impact on society beyond science and technology?**
  Nothing to report.

5. CHANGES/PROBLEMS

- **Changes in approach and reasons for change**
  No changes to report.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  Initially, there were delays in the IRB approval process due to the multicenter nature of the project. The IRB specialists at Mayo and NMCSD provided conflicting information to the investigators regarding how the approval process should be conducted. After numerous discussions between the investigators and with both IRBs, the issues have been resolved and protocol reviews are underway at NMCSD and completed at Mayo. Nonetheless, this delayed the time for receiving regulatory approval.

- **Changes that had a significant impact on expenditures**
  Nothing to report.

- **Significant changes in use or care of human subjects**
  None.

6. PRODUCTS

- **Publications, conference papers, and presentations**
  Nothing to report.

- **Website(s) or other Internet site(s)**
  Nothing to report.

- **Technologies or techniques**
  Nothing to report.

- **Inventions, patent applications, and /or licenses**
  Nothing to report.

- **Other products**
  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Kenton Kaufman, PhD, PE
Project Role:	Principal Investigator, Mayo Clinic
Nearest person month worked:	2
Contribution to Project:	Dr. Kaufman has held regular meetings with the Co-Investigators. He has prepared materials for submission to the Mayo IRB, HRPO. He has worked to develop the standard operating procedures for the research protocols. He has served as the liaison with the Grants Officer's Representative and has proved the required quarterly and annual reports.
Funding Support:	

Name:	Leah Taylor, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	3
Contribution to Project:	Leah has worked on the static and dynamic Inertial Measurement Unit (IMU) validation. She has also started preparing a manuscript on the IMU accuracy and precision to be submitted after testing completion.
Funding Support:	

Name:	Emily Miller, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	3
Contribution to Project:	Emily Miller has attended regular meetings with Co-Investigators. She has prepared materials for submission to the Mayo IRB, conducted equipment tests, and developed code to analyze data to validate the IMUs to Motion Analysis to measure trunk flexion and angular velocity. She has developed custom software to implement the controlled disturbances on the AMTI treadmill utilized in the training program and written a user's manual.
Funding Support:	

Name:	Christine Huyber, CCRP
Project Role:	Study Coordinator, Mayo Clinic
Nearest person month worked:	1
Contribution to Project:	Christine Huyber has attended regular meetings with Co-Investigators. She has prepared materials for submission to the Mayo IRB. She has developed surveys for subjects in the study and data collections tools for use across institutions

	within REDCap.
Funding Support:	

Name:	Marilynn Wyatt, MA, PT
Project Role:	Site Principal Investigator, NMCSD
Nearest person month worked:	1
Contribution to Project:	Ms. Wyatt is the NMCSD site principal investigator for the project. She has attended all study meetings and coordinated the sub-award with the Geneva Foundation. She has worked with staff to prepare a CRADA document that has been signed by NMCSD, NHRC, Mayo Clinic and Geneva Foundation. She has submitted multi-site IRB protocol documents to cover this project for the three DoD sites. She has finalized the SOP for the project. She has hired an engineer and research physical therapist to work on this project through the Geneva Foundation. Work has begun coordinating the programming of the instrumented treadmill with Mayo Clinic staff and preliminary testing of the IMU sensors (ADPM) with NHRC and NMCSD staff.
Funding Support:	Federal Employee

Name:	Jason Wilken, PT, PhD
Project Role:	Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Wilken has contributed to multiple meetings with the study team, contributing to the selection of study measures and refinement of study procedures. He has contributed to activities associated with study specific purchases, regulatory approvals and initiation of a cooperative research agreement.
Funding Support:	Federal Employee

Name:	Mark D. Grabiner, PhD
Project Role:	Site Principal Investigator, University of Illinois-Chicago
Nearest person month worked:	2
Contribution to Project:	Dr. Grabiner has participated in the regularly scheduled research-team conference calls and attended the research team meeting in August 2016. He has hired, and coordinates the effort on this project of a 0.25 FTE doctoral student. The project-based work at UIC is focused on post-collection analysis of biomechanical data collected at and transferred from Mayo, NMCSD, CFI, and WRNMMC.
Funding Support:	

Name:	Christopher L. Dearth, PhD
Project Role:	Site Principal Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Dearth serves as the WRNMMC site lead for the project. During the current reporting period, Dr. Dearth has

	participated in all study meetings with other Co-Investigators, coordinated the sub-award documentation with HJF, lead the effort to purchase equipment for the study, engaged in discussions with WRNMMC clinical and research staff members regarding the protocol, and assisted with the creation of documentation for the clinical research protocol that was submitted to the NMCSD IRB.
Funding Support:	

Name:	Bradford D. Hendershot, PhD
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Hendershot serves as an Associate Investigator for the project. During the current reporting period, Dr. Hendershot has engaged in discussions with WRNMMC clinical and research staff members regarding the protocol, and assisted with the creation of documentation for the clinical research protocol that was submitted to the NMCSD IRB. Dr. Hendershot has attended all project meetings, assisted with the creation of the testing SOP, and advised on the addition of a trunk postural control test. He has also assisted with regulatory documentation for the IRB.
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  No.

- **What other organizations were involved as partners?**
  Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

- **Collaborative Awards**

- **Quad Chart**

9. APPENDICES